

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0394945	(X3) Date Survey Completed 03/21/2022
Name of Provider or Supplier N E W Community Clinic, Ltd	Street Address, City, State 610 N Broadway Street, Green Bay, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the "Wet Prep" procedure and interview with the laboratory director the procedure did not include reporting instructions for four of five cellular elements, did not include reference values, and did not describe the course of action to take if the test system is inoperable. Findings include: 1. The "Wet Prep" procedure included instructions to examine the prepared slide for trichomonads, clue cells, WBCs (White Blood Cells), RBCs (Red Blood Cells), and yeast. The interpretation section of the procedure includes instruction to report clue cells as positive or negative. There are no other instructions for reporting results of the wet</p>

prep evaluation. 2. The procedure did not include expected normal or reference values. 3. The procedure did not describe the steps to take if the test system is inoperable. 4. Interview with the laboratory director on March 21, 2021 at 11:45 AM confirmed the procedure did not include instructions for reporting the results of the wet prep evaluation.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on surveyor review of personnel records and interview with the laboratory director, the technical consultant did not evaluate competency in 2020 or 2021 for one of one testing person at the N E W Community Clinic 2740 W Mason Street location. Findings include: 1. Review of training and competency records from 2020 and 2021 showed no documented direct observation of routine patient testing or maintenance, no evaluation of problem-solving skills or monitoring of patient results for staff A. 2. Interview with the laboratory director on March 21, 2022 at 11:00 AM confirmed the technical consultant did not evaluate competency of staff A using the elements required at 493.1413(b)(8) in 2020 or 2021. This is a repeat deficiency previously cited on April 15, 2010.